- --96. (New) An absorption promoting and/or gastric emptying slowing composition, comprising
- a first component comprising an active ingredient to be absorbed through the stomach, a second component comprising an amount of a carrier-dispersible form of an active lipid, said active lipid being selected from the group consisting of:
 - (A) saturated and unsaturated fats;
 - (B) fully hydrolyzed fats;
 - (C) pharmaceutically acceptable salts of any of (A) or (B); and
 - (D) a mixture of any of (A), (B), or (C).
- 97. (New) The absorption promoting and/or gastric emptying slowing composition of claim 96, wherein the amount of the active lipid is about 0.5 to about 25 grams per dose.
- 98. (New) The absorption promoting and/or gastric emptying slowing composition of claim 96, formulated for oral delivery.
- 99. (New) The absorption promoting and/or gastric emptying slowing composition of claim 96, wherein the active ingredient is selected from the group consisting of pharmacological agents.
- 100. (New) The absorption promoting and/or gastric emptying slowing composition of claim 99, wherein the pharmacological agents are selected from the group consisting of somatostatin analogues, insulin release inhibitors, anti-diarrheal agents, antibiotics, fiber, electrolytes, analgesics, antipyretics, migraine treatment, migraine prophylaxis, antifungal agents, antiviral agents, Quinolones, AIDS therapeutic agents, anti-infectives, aminoglycosides, antispasmodics, parasympathomimetics, anti-tuberculous agents, anti-malarial agents, vaccines, anti-parasitic agents, cephalosporins, macrolides, azalides, tetracyclines, penicillins, anti-arthritic therapy agents, gout therapy agents, nonsteroidal anti-inflammatory agents, gold compounds, antianemic agents, antianginal agents, antiarrhythmics, anticoagulants, post-MI agents, vasodilators, beta-adrenergic blockers, calcium channel blockers, nitrates, thrombolytic agents, anticoagulants, antifibrolytic agents, hemorrheologic agents, antiplatelet agents, vitamins, antihemophilic agents, heart failure agents, ACE inhibitors, cardiac glycosides, blood flow



modifying agents, bile salts, growth promoting agents, growth suppressive agents, sympathomimetics, inotropic agents, antihypertensive agents, central alpha-adrenergic agonists, peripheral vasodilator, sympatholytics, diuretics, diuretic combinations, mineral supplements, hypolipedemic agents, acne treatments, antidiarrheal agents, antinauseants, antiemetics, antispasmodics, antiulcer, antireflux agents, appetite suppressants, appetite enhancers, gallstonedissolving agents, gastrointestinal anti-inflammatory agents, antacids, antiflatulents, anti-gas agents, laxatives, stool softeners, digestants, digestive enzymes, enzyme supplements, Alzheimer's therapy, anticonvulsants, antiparkinson agents, sedatives, benzodiazepines, benzodiazepine receptor antagonists, receptor agonists, receptor antagonists, interferons, immunosuppressive therapy, immunomodulatory agents, muscle relaxants, hypnotics, antianxiety agents, antimanic agents, antidepressants, antiobesity agents, behavior modifiers, psychostimulants, neurostimulants, abuse deterrents, anxiolytics, antipsychotics, antianaphylactic agents, antihistamines, antipruritics, anti-inflammatory agents, bronchodilators, antiasthmatic agents, cystic fibrosis therapy agents, mast-cell stabilizers, steroids, xanthines, anticholinergic agents, bioactive peptides, polypeptides, hormones, drugs acting at neuroeffector junctional sites, prostaglandins, narcotics, hypnotics, alcohols, psychiatric therapy agents, anti-cancer chemotherapy agents, drugs affecting motility, oral hypoglycemics, androgens, estrogens, nutriceuticals, herbal medications, insulin, serotonin receptor agonist, serotonin receptor antagonists, alternative medicines, amino acids, dietary supplements, analeptic agents, respiratory agents, cold remedies, cough suppressants, antimycotics, bronchodilators (constipation aids), contraceptives, decongestants, expectorants, motion sickness products, and homeopathic preparations.

101. (New) The absorption promoting and/or gastric emptying slowing composition of claim 96, further comprising an additional ingredient selected from the group consisting of carriers, excipients, vehicles, lipid dispersants, detergents, bile acid salts, and suspending agents, emulsifying agents, stabilizing agents, thickening agents, buffering agents, preserving agents, coloring agents, disintegrating agents, solubilizing agents, flavoring agents, and sweetening agents.

S/X

102. (New) The absorption promoting and/or gastric emptying slowing composition of claim 101, wherein the carrier is selected from the group consisting of glucose, lactose, gum acacia, gelatin, mannitol, starch paste, magnesium trisilicate, talc, corn starch, keratin, colloidal silica, potato starch, urea, medium chain length triglycerides and dextrans.

PATENT

103. (New) The oral formulation of claim 98, being in a form selected from the group consisting of capsules, coated and uncoated microspheres and particles, which may be encapsulated, coated or uncoated tablets, troches, lozenges, aqueous and oily suspensions, dispersible powders and granules, emulsions, hard and soft capsules, syrups and elixirs.

- 104. (New) A controlled release formulation, comprising the absorption promoting and/or gastric emptying slowing composition of claim 96, and a controlled release coating.
- 105. (New) A slow release formulation, comprising the absorption promoting and/or gastric emptying slowing composition of claim 96, and a slow release coating.
- 106. (New) The absorption promoting and/or gastric emptying slowing composition of claim 96, wherein the active lipid is selected from the group consisting of (C₄ to C₂₄) fatty acids, pharmaceutically acceptable salts thereof, and mixtures of either of these.
- 107. (New) The absorption promoting and/or gastric emptying slowing composition of claim 106, wherein the active lipid is selected from the group consisting of:
- (A) caprolic acid, caprulic acid, capric acid, lauric acid, myristic acid, oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, linolenic acid, trans-hexadecanoic acid, elaidic acid, columbinic acid, arachidic acid, behenic acid, eicosenoic acid, erucic acid, bressidic acid, cetoleic acid, nervonic acid, Mead acid, arachidonic acid, timnodonic acid, clupanodonic acid, or docosahexaenoic acid,
 - (B) pharmaceutically acceptable salts of any of (A); and
 - (C) and mixtures of any of (A) or (B).

PATENT

P07 43084 (18810-80389)

108. (New) The absorption promoting and/or gastric emptying slowing composition of claim 107, wherein the active lipid consists of oleic acid, a pharmaceutically acceptable oleate salt, or a mixture of either of these with other fatty acids or salts thereof.

- 109. (New) A method of delaying gastric emptying and promoting absorption, comprising administering orally to a subject in need of treatment at least one dose of the composition of claim 96, wherein the active ingredient is absorbed through the stomach in undegraded form and, thereby, increases residence time of the active ingredient in the stomach.
- 110. (New) The method of claim 109, wherein the active lipid triggers at least one reflex selected from the group consisting of intestino-lower esophageal sphincter or relaxation of LES reflex, intestino-gastric feedback or inhibition of gastric emptying reflex, intestino-intestinal feedback or ileo-jejunal feedback/ileal brake reflex, jejuno-jejunal feedback/jejunal brake reflex, conversion to fed motility reflex, intestino-CNS feedback or satiety intensifying intestinal signaling reflex, intestino-pancreatic feedback or exocrine enzyme output control reflex, intestino-biliary feedback or bile flow control reflex, intestino-mesenteric blood flow feedback reflex for mucosal hyperemia control and intestino-colonic feedback, gastro-colonic reflex or colon contracting response to nutrients, in the proximal segment of the small intestine.
- 111. (New) The method of claim 109, wherein the active lipid is administered in an amount of about 0.5 to about 25 grams per dose.
- 112. (New) A method of enhancing bioavailability of pharmaceutical preparations comprising administering to a subject at least one dose of the absorption promoting and/or gastric emptying slowing composition of claim 96, in an amount and in a form effective to deliver the active lipid to the subject's stomach and, thereby, increase absorption of pharmacological agents through the subject's stomach.
- 113. (New) The method of claim 112, wherein the active lipid is administered in an amount of about 0.5 to about 25 grams per dose.



P07 43084 (18810-80389) PATENT

114. (New) An anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition, comprising:

a first component comprising an <u>active ingredient</u> to be absorbed through the stomach and small intestine;

a second component comprising an amount of a carrier dispersible form of an active lipid selected from the group consisting of

- (A) saturated and unsaturated fats;
- (B) fully hydrolyzed fats;
- (C) pharmaceutically acceptable salts of any of (A) or (B); and
- (D) a mixture of any of (A), (B), or (C).

115. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, wherein the amount of the active lipid is about 0.5 to about 25 grams per dose.

- 116. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, formulated for oral delivery.
- 117. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting, and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, wherein the active ingredient is selected from the group consisting of nutrients and pharmacological agents.
- 118. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 117, wherein the nutrient is selected from the group consisting of foodstuffs, vitamins and minerals.



The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or 119. (New) absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 117, wherein the pharmacological agent is selected from the group consisting of somatostatin analogues, insulin release inhibitors, anti-diarrheal agents, antibiotics, fiber, electrolytes, analgesics, antipyretics, migraine treatment, migraine prophylaxis, antifungal agents antiviral agents, Quinolones, AIDS therapeutic agents, anti-infectives, aminoglycosides, antispasmodics, parasympathomimetics, anti-tuberculous agents, anti-matarial agents, vaccines, ahti-parasitic agents, cephalosporins, macrolides, azalides, tetracyclines, penicillins, anti-arthritic therapy agents, gout therapy agents, nonsteroidal anti-inflammatory agents, gold compounds, antianemic agents, antianginal agents, antiarrhythmics, anticoagulants, post-MI agents, vasodilators, beta-adrenergic blockers, calcium channel blockers, nitrates, thrombolytic agents, anticoagulants, antifibrolytic agents, hemorrheologic agents, antiplatelet agents, vitamins, antihemophilic agents, heart failure agents, ACE inhibitors, cardiac glycosides, blood flow modifying agents, bile salts, growth promoting agents, growth suppressive agents, sympathomimetics, inotropic agents, antihypertensive agents, central alpha-adrenergic agonists, peripheral vasodilator, sympatholytics, diaretics, diuretic combinations, mineral supplements, hypolipedemic agents, acne treatments, antidiarrheal agents, antinauseants, antiemetics, antispasmodics, antiulcer, antireflux agents, appetite suppressants, appetite enhancers, gallstonedissolving agents, gastrointestinal anti-inflammatory agents, antacids, antiflatulents, anti-gas agents, laxatives, stool softeners, digestants, digestive enzymes, enzyme supplements, alzheimer ls therapy, anticonvulsants antiparkinson agents, sedatives, benzodiazepines, benzodiazepine receptor antagonists. receptor agonists, receptor antagonists, interferons, immunosuppressive therapy, immunomodulatory agents, muscle relaxants, hypnotics, antianxiety agents, antimanic agents, antidepfessants, antiobesity agents, behavior modifiers, psychostimulants, neurostimulants, abuse deterrents, anxiolytics, antipsychotics, antianaphylactic agents, antihistamines, antipruritics, anti-inflammatory agents, bronchodilators, antiasthmatic agents, cystic fibrosis therapy agents, mast/cell stabilizers, steroids, xanthines, anticholinergic agents, bioactive peptides, polypeptides, hørmones, drugs acting at neuroeffector junctional sites, prostaglandins, narcotics, hypnotics,

SVB CI, alcohols, psychiatric therapy agents, anti-cancer chemotherapy agents, drugs affecting motility, oral hypoglycemics, androgens, estrogens, nutriceuticals, herbal medications, insulin, serotonin receptor agonist, serotonin receptor antagonists, alternative medicines, amino acids, dietary supplements, analeptic agents, respiratory agents, cold remedies, cough suppressants, antimycotics, bronchodilators, constipation aids, contraceptives, decongestants, expectorants, motion sickness products, and homeopathic preparations.

- 120. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting, and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, further comprising an additional ingredient selected from the group consisting of carriers, excipients, vehicles, lipid dispersants, detergents, bile acid salts, and suspending agents, emulsifying agents, stabilizing agents, thickening agents, buffering agents, preserving agents, coloring agents, disintegrating agents, solubilizing agents, flavoring agents, and sweetening agents.
- 121. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 120, wherein the carrier is selected from the group consisting of glucose, lactose, gum acacia, gelatin, mannitol, starch paste, magnesium trisilicate, talc, corn starch, keratin, colloidal silica, potato starch, urea, medium chain length triglycerides and dextrans.
- 122. (New) The oral formulation of claim 116, being in a form selected from the group consisting of capsules, coated and uncoated microspheres and particles, which may be encapsulated, coated or uncoated tablets, troches, lozenges, aqueous and oily suspensions, dispersible powders and granules, emulsions, hard and soft capsules, syrups and elixirs.
- 123. (New) A controlled release formulation, comprising the anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting, and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, and a controlled release coating.

8

P07 43084 (18810-80389)

- 124. (New) A slow release formulation, comprising the anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting, and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, and a slow release coating.
- 125. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, wherein the active lipid is selected from the group consisting of (C4 to C24) fatty acids, pharmaceutically acceptable salts thereof, and mixtures of either of these.
- 126. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 125, wherein the active lipid is selected from the group consisting of:
- (A) caprolic acid, caprulic acid, capric acid, lauric acid, myristic acid, oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, linolenic acid, trans-hexadecanoic acid, elaidic acid, columbinic acid, arachidic acid, behenic acid, eicosenoic acid, erucic acid, bressidic acid, cetoleic acid, nervonic acid, Mead acid, arachidonic acid, timnodonic acid, clupanodonic acid, or docosahexaenoic acid,
 - (B) pharmaceutically acceptable salts of any of (A); and
 - (C) and mixtures of any of (A) or (B).
- 127. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 126, wherein the active lipid consists of oleic acid, a pharmaceutically acceptable oleate salt, or a mixture of either of these with other fatty acids or salts thereof.
- 128. (New) A method of delaying gastric emptying and prolonging small intestine transit time while promoting an anti-atherogenic and/or anti-diarrheal effect and/or promoting digestion, dissolution and/or absorption, comprising administering to a subject in need of treatment at least one dose of the composition of claim 114, wherein the active ingredient is absorbed through the stomach and proximal segment of the small intestine in undegraded form and, thereby, increases residence time of the active ingredient in the stomach and decreases small



P07 43084 (18810-80389)

intestine transit time of the active ingredient and produces an anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing effect.

- 129. (New) The method of claim 128, wherein the active lipid triggers at least one reflex selected from the group consisting of intestino-lower esophageal sphincter or relaxation of LES reflex, intestino-gastric feedback or inhibition of gastric emptying reflex, intestino-intestinal feedback or ileo-jejunal feedback/ileal brake reflex, jejuno-jejunal feedback/jejunal brake reflex, conversion to fed motility reflex, intestino-CNS feedback or satiety intensifying intestinal signaling reflex, intestino-pancreatic feedback or exocrine enzyme output control reflex, intestino-biliary feedback or bile flow control reflex, intestino-mesenteric blood flow feedback reflex for mucosal hyperemia control and intestino-colonic feedback, gastro-colonic reflex or colon contracting response to nutrients, in the proximal segment of the small intestine.
- 130. (New) The method of claim 128, wherein the active lipid is administered-in anamount of about 0.5-to-about 25 grams per dose.
- 131. (New) A method of treating a nutritional deficiency or medical condition comprising administering to a subject afflicted with a nutritional deficiency or medical condition at least one dose of the anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 114, in an amount and in a form effective to deliver the active lipid to the subject's stomach and proximal segment of the small intestine and, thereby, increase absorption of nutrients or pharmacological agents through the subject's stomach and small intestine.
- 132. (New) The method of claim 131, wherein the subject's nutritional deficiency is associated with gastrointestinal symptoms selected from the group consisting of rapid intestinal transit, dumping syndrome, diarrhea, weight loss, distention, steatorrhea, asthenia, poor bioavailability of oral drugs, and symptoms of specific nutrient deficiencies.

associated with a gastrointestinal disorder selected from the group consisting of post-gastrectomy syndrome, dumping syndrome, AIDS-associated chronic diarrhea, diabetes-associated diarrhea, post-vagotomy diarrhea, bariatrics surgery-associated diarrhea, short bowel syndrome, tube-feeding related diarrhea, chronic secretory diarrhea, carcinoid syndrome-associated diarrhea, gastrointestinal peptide tumors, endocrine tumors, chronic diarrhea associated with thyroid disorders, chronic diarrhea associated with bacterial overgrowth, chronic diarrhea in gastronomy, choleraic diarrhea, chronic diarrhea associated with giardiasis, antibiotic-associated chronic diarrhea, diarrhea-predominant irritable bowel syndrome, diarrhea associated with disordered gastrointestinal motility, chronic diarrhea associated with maldigestion and malabsorption, chronic diarrhea associated with idiopathic primary gastrointestinal motility disorders, chronic diarrhea associated with collagenous colitis, surgery-associated acute diarrhea, antibiotic-associated acute diarrhea and infection-associated acute infectious diarrhea.



- 134. (New) The method of claim 131, wherein the bariatrics surgery-associated diarrhea comprises obesity surgeries selected from the group consisting of gastric bypass, gastroplasties and intestinal bypass.
- from the group consisting of including resection of the small intestine, radiation induced complications, Crohn's disease and infarction of the intestine associated with vascular occlusion.
- 136. (New) The method of claim 131, wherein the active lipid is administered in an amount of about 0.5 to about 25 grams per dose.
- 137. (New) The anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing composition of claim 96, wherein both the active lipid and the active ingredient are formulated for

